EVALUATION OF A NOVEL TOURNIQUET DEVICE FOR BLOODLESS SURGERY OF THE HAND

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This study evaluates a new device (S-MART™) for exsanguination and occlusion of the blood flow to the arm for hand surgery. The device consists of a silicone ring wrapped within a sterile stockinette and pull straps. It is applied by placing it on the patient's fingers and rolling it up the limb to the desired occlusion site by pulling on the straps. The time for placement and removal of the device was measured during trigger release and carpal tunnel surgery and the quality of exsanguination was evaluated. The device could be placed and removed quickly and provided an excellent bloodless field. At follow-up examination no signs or symptoms were seen at the site of the S-MART™ occlusion and no complications were observed in any patient.
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INTRODUCTION

Surgical procedures on the upper and lower extremities are most often performed using a tourniquet (Wright Philips, 1981). Exsanguination is usually done by tightly wrapping an Esmarch bandage around the limb starting from its distal end, after which a pneumatic cuff is inflated around the proximal limb (Pedowitz, 1991; Reid et al., 1983; Wakai et al., 2001). The aim of the present study is to evaluate a new device, S-MART™ (OHK Medical Devices, Haifa, Israel) for exsanguination and occlusion of the blood flow to the arm.

The evaluation of the device in this study consisted of measurement of the time taken to apply and remove the device, the effort required for placement of the device, rating of exsanguination during the procedure, and a postoperative follow-up.

METHODS AND MATERIALS

The local ethics committee of Carmel Medical Center approved the study protocol. Following informed consent, patients undergoing hand surgery were recruited into the study. Exclusion criteria were a limb circumference at the occlusion site of greater than 40 cm or smaller than 20 cm, a systolic blood pressure in excess of 190 mmHg, open skin lesions and an unstable (e.g. fractured) limb.

The patients were recruited consecutively from operation lists conducted in the hospital's out-patient facility. All the procedures were performed by a single surgeon (MB).

The S-MART™ (OHK Medical Devices, Haifa, Israel) consists of a silicone ring (internal diameter 52 mm, external diameter 76 mm) wrapped within an elastic sleeve (stockinette) and two straps attached to pull handles (Fig 1). The device is inserted over the patient's fingers (Fig 2) and is then rolled proximally up the limb (Fig 3) by pulling the handles towards the desired occlusion site (Fig 4). As the device rolls proximally, it compresses the limb and expels blood from the extremity into the central circulation. When the device is positioned at the proximal occlusion location (mid-forearm for hand and wrist surgery; upper arm for tendon and elbow surgery), it continues to exert supra-systolic pressure on the limb which prevents arterial flow. During the rolling of the ring onto the limb, the sterile stockinette unfolds to provide a sterile draping (Fig 4).

The S-MART™ comes in two sizes: a small size for the arm and a large size for the leg and for large arms (circumference at occlusion site greater than 40 cm). Each size has three colour-coded tension models, each providing occlusion for different ranges of blood pressure: Green (G): up to 130 mmHg; Red (R): 130 to 160 mmHg; Yellow (Y): 160 to 190 mmHg.

The device is sterile and double packaged. When used on an arm, the device applies a skin pressure of 250 to 350 mmHg, depending on the model chosen (see below) and the actual limb circumference. In larger diameter limbs that require somewhat higher pressure to occlude the arterial circulation, the applied pressure is self-adjusted and is higher than in thin limbs. The applied pressure is factory pre-set and cannot be changed once the device is on the patient.

Each patient received the appropriate model according to the systolic blood pressure measured in the operating room directly before the placement of the device.

A case report form was completed by the surgeon and assessed the ease of device placement on a 1 to 10 scale (1 = very easy, 10 = very difficult) and the visual quality of surgical site (1 = unacceptable, 2 = poor, 3 = fair, 4 = good, 5 = excellent).

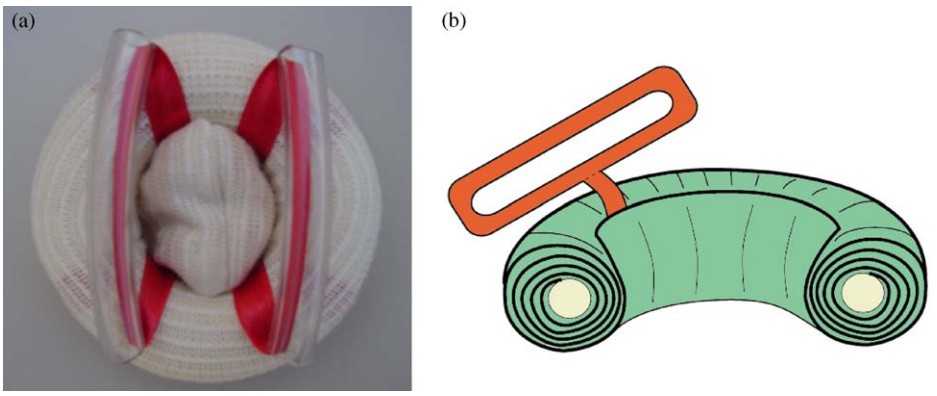

Fig 1 S-MART:arm.

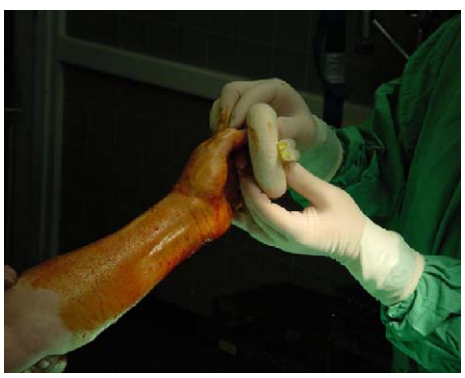

Fig 2 Placed on the fingers.

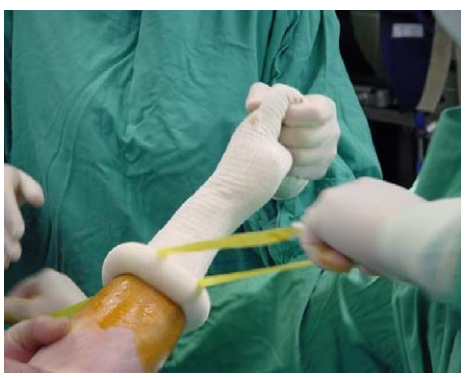

Fig 3 Pulled up the arm.

The surgical procedures were all performed under local anaesthesia by local infiltration of the tissues; a brachial block was never used. The hand and arm were prepared with a Betadine solution to about 5 to 10 cm beyond the anticipated site of the occluding ring. The S-MART™ was then applied by pulling on its handles until the ring reached the occlusion location. The stockinette over the hand was then cut and pulled up the arm and the surgical procedure was performed. The tourniquet was released according to the manufacturer's instructions, by cutting the silicone ring and the elastic sleeve of the device.

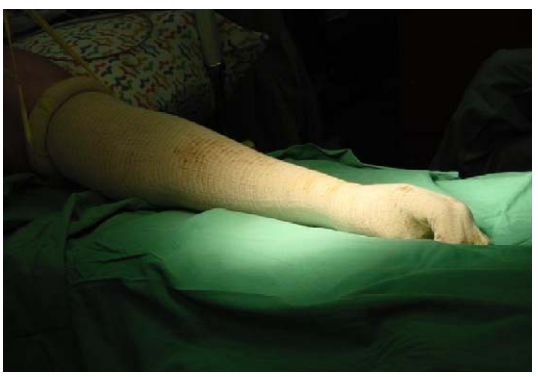

Fig 4 Final occlusion position.

RESULTS

There were nine men and nine women with an average age of 63 (range, 45–82) years who underwent either trigger digit or carpal tunnel release. All their arms had a limb circumference of between 20 and 40 cm, the allowable range for the S-MART™.

The placement score was 1 or 2 (out of 10) in all but one patient whose score was rated at 3 by the surgeon. The longest placement time was 15 seconds, with 10 seconds being the typical time.

The original plan was to measure the blood loss at the surgical site during the surgery by weighing the gauze swabs. However, in all but one patient, the blood loss was minimal and could not be measured. In the other patient the blood loss was 5 ml.

The device was applied for a mean of 14 (range, 6–27) minutes. No deterioration in the visual quality in the surgical site was noted during any of the operations and

the device was tolerated well by all the patients. No analgesia was needed to counteract the compression discomfort. Follow-up examination was performed 8 days following the operation according to a standard postoperative protocol for hand surgery procedures. No symptoms or signs at the site of the S-MART occlusion and no complications were observed in any of the patients.

DISCUSSION

The S-MART™ performed very well in carpal tunnel and trigger digit release procedures. Its major advantages over conventional methods are the visual quality of the surgical field, the ease and speed of application and the fact that the device is sterile and applied after skin preparation and draping, thus shortening the tourniquet time. Also the placement and removal of the device are quickly done by the surgeon alone, eliminating the need for assistance from the operating room staff.

The preferred site for the S-MART™ for most surgery on the hand is the forearm. Tendon surgery or complex soft tissue reconstruction procedures (as well as elbow surgery) need placement of the device on the upper arm. Placement of the device near the surgical field is possible because the S-MART™ is sterile and effectively occludes the blood flow at the forearm location.

The device is well-tolerated by patients but a quantitative, comparative evaluation of the pain caused by the S-MART™ device and a standard pneumatic cuff is required. The concentric force of the elastic silicone ring is evenly distributed around the limb circumference, thus reducing the skin wrinkling which often occurs with pneumatic tourniquets. Furthermore, some of the stockinette stays wrapped around the ring and provides a built-in cushion that further reduces the impact of the device on the skin. No skin lesions were observed after the operation or at follow-up.

The tension of the device is factory pre-set to 250 to 350 mmHg at the skin surface, depending on the model (colour coded) and the patient's limb circumference. Unlike a standard pneumatic cuff, it is not possible to adjust the pressure during the operation, and thus an increase in the blood pressure during the operation could cause leakage of blood under the ring and bleeding at the surgical site. If this is a concern, it is possible to select a model that is suitable for a higher blood pressure than that measured at the beginning of the procedure. No leaks were seen in any of our patients whose blood pressure fluctuations during the procedure were within the blood pressure range for each model.

Another difference between the S-MART™ and standard tourniquets is that the pressure cannot be released temporarily during the procedure. The device is removed by cutting the ring which cannot be re-attached. While the cases in the present group were short, we recommend that the S-MART™ should not be applied for more than 2 hours, as for a pneumatic tourniquet (Pedowitz, 1991). As the current device cannot be used for limbs that have a circumference less than 20 cm, it is not suitable for children or small people. Other limitations are that it should not be used on unstable (fractured or dislocated) limbs or on patients with venous thrombosis (to avoid the risk of embolization).

Acknowledgements

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References

Pedowitz RA (1991). Tourniquet-induced neuromuscular injury. A recent review of rabbit and clinical experiments. Acta Orthopedica Scandinavia, 62 (Suppl 245): 1–33.

Reid HS. et al. (1983). Tourniquet hemostasis. A clinical study. Clinical Orthopaedics and Related Research, 177: 230–234.

Wakai A et al. (2001). Pneumatic tourniquets in extremity surgery. Journal of American Academy of Orthopedic Surgeons, 9: 345–351.

Wright Philip E. Basic surgical technique and aftercare. In: Tubiana R (Ed) *The hand*. Philadelphia, WB Saunders, 1981, Vol. 15: 3273–3293.

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